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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,665

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Hiraku Murayama

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

NOTIFICATION DATE

DELIVERY MODE

12/17/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/635,665	Applicant(s) MURAYAMA ET AL.	
	Examiner JEFFREY G. HOEKSTRA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 12-21, 23-28, 30 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 12-21, 23-28, 30 and 32-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/2008 has been entered.

Notice of Amendment

2. In response to the amendment filed on 11/12/2008, amended claim(s) 1, 24, and 28 is/are acknowledged. The previous rejections of claims 1-3, 12-21, 23-28, 30, and 32-35 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, 12-15, 16-18, 23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo et al. (US 5,769,796, hereinafter Palermo) in view of Reynolds et al. (US 7,074,197 B2, hereinafter Reynolds).

5. Palermo discloses a guidewire (140) (as best seen in Figures 2 and 5A) (column 4 lines 26-32, column 5 lines 45-65, column 6 line 39 – column 7 line 18, and column 8 –line 50 – column 10 line 54), comprising:

- a distally disposed reshapeable and non-superelastic metallic first wire (126) (as best seen in Figure 5A) (the stainless steel as positively recited in column 6 line 39 – column 7 line 18) having a proximal tip (the left tip as best seen in Figure 5A), having a length of 30mm (column 5 lines 19-22), is not being a coil (as best seen in Figure 5A), and that is capable of being plastically deformed to a desired shaped being and capable of being maintained in the desired shape upon being bent in the desired shape by a user;
- an intermediately disposed pseudo-elastic alloy second wire (146) (column 4 lines 26-32, column 5 lines 45-65, and the pseudo-elastic Nitinol alloy positively recited in column 8 –line 50 – column 10 line 54) (as best seen in Figure 2) having a smaller elastic modulus than the first wire) (column 8 –line 50 – column 10 line 54) and a distal tip (the right tip as best seen in Figure 2),
- wherein said first and second wires have a common longitudinal axis (as best seen in Figure 5A), are coaxial (as best seen in Figure 5A), and are joined at a joined portion (as best seen in Figure 5A) of the end faces of the fir5st and second wires in a nearly perpendicular orientation with respect to the longitudinal axis (as best seen in Figure 5A);

- a proximally disposed third wire (142) (the stainless steel positively recited in column 5 lines 45-65) having a larger elastic modulus than the elastic modulus of the material forming the second wire (column 5 lines 45-65);
- wherein the second and third wire are joined to each other (column 5 lines 45-65) (as best seen in Figure 2) and wherein the guidewire has a taper extending from the proximal end to the distal end (as best seen in Figure 2); and
- a spiral coil (112) (as best seen in Figures 2 and 5A) (column 6 line 39 – column 7 line 18) covering at least the distal end portion of the first wire (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein the joined portion between the first and second wires is located distal the proximal end of the spiral coil (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein the coil covers the joined portion and is spaced outwardly away from the joined portion (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein at least a portion of the spiral coil is located distally beyond a distal end of the joined portion (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein the spiral coil possess an axial extent greater than an axial extent of welded portion (as best seen in Figure 5A) (column 6 line 39 – column 7 line 18), wherein the spiral coil is fixed at an intermediate portion to the first wire with a first fixing material (128) (as best seen in Figure 5B) (column 6 line 39 – column 7 line 18), and wherein a second fixing material (110) (column 6 line 39 – column 7 line 18) fixes the distal end portion of the spiral coil to the first wire (as best seen in Figure 5A),

- wherein said guidewire ranges in length from 10 to 1,000 mm (column 5 lines 13-17).

6. Palermo discloses the claimed guidewire, as set forth and cited above, except for expressly disclosing that (a) the joined portion comprises a welded portion, wherein the welded portion is created by spot or butt-resistance welding and (b) wherein the joined portion between the first and second wires is located proximal the proximal end of the spiral coil. However, Palermo is expressly concerned with joining and/or attaching the guidewire components (e.g. first, second, and/or third wires) and with regards to said joining and/or attaching explicitly states *inter alia* "attached by soldering or by gluing or by other joining method suitable for the materials involved" (column 5 lines 56-60).

Furthermore, the Examiner notes it is well known in the guidewire art to substitute one joining and/or attaching means for another to achieve the predictable result of securely joining and/or attaching adjacent wires.

7. Reynolds teaches a guidewire (310) (as best seen in Figure 11) comprising *inter alia*: a joined portion between a first (316) and a second wire (314) comprising a welded portion (312) comprising a fused layer (as best seen in Figure 11), wherein the welded portion is created by spot or butt-resistance welding (column 7 lines 27-65,) and (b) wherein the joined portion between the first and second wires is located proximal the proximal end of a spiral coil (380) (as best seen in Figure 11) (column 13 line 1 – column 14 line 3).

8. Thus for claims 1-3, 12-15, 16-18, 23, and 28, the claimed invention would have been obvious because the substitution of one known element for another would have

yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Palermo and Reynolds teach joining methods for components of guidewires, it would have been obvious to one skilled in the art at the time of the invention to substitute one joining method for the other to achieve the predictable results of securely joining two adjacent wire components of a composite guidewire.

Response to Arguments

9. Applicant's arguments with respect to claims 1-3, 12-21, 23-28, 30, and 32-35 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736